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EXAMINER
ZISKA, S

ART UNIT	PAPER NUMBER
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DATE MAILED: 04/06/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 (0) month(s), 30 (thirty) days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-78 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-78 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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PTO-326 (Rev. 2/93) **EXAMINER'S ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method for producing a xenogeneic immunoglobulin or analog thereof in a non-human animal comprising immunizing the animal, classified in Class 424, subclass 88, for example.

II. Claims 11-14, drawn to an immortalized non-human cell line genetically modified so as to lack the ability to produce immunoglobulin endogenous to the cell, classified in Class 435, subclass 172.2 and Class 435, subclass 172.3, for example.

III. Claims 15, 70 and 71, drawn to a xenogeneic immunoglobulin, classified in Class 530, subclass 387.1+, for example.

IV. Claims 16-26 and 75-78, drawn to a genetically modified non-human animal having a modified genome, classified in Class 800, subclass 2, for example.

V. Claims 27-33, drawn to a method for producing a modified non-human animal having a xenogeneic DNA segment of at least 100 kb stably integrated into the genome comprising fusing yeast spheroplasts to embryonic stem cells, classified in Class 435, subclasses 172.2, and 172.3, for example.

VI. Claims 34-39, 68, 69, drawn to a modified non-human animal heterozygous or homozygous for a xenogeneic genomic mammalian DNA segment stably integrated (using YACS) into the genome, classified in Class 800, subclass 2, for example.

VII. Claims 40-56, drawn to embryonic stem cells having a genome comprising a lesion in the endogenous immunoglobulin heavy chain and/or light chain loci, classified in Class 800, subclass 2, for example.

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VIII. Claims 57-59, 67, drawn to a murine embryonic stem cell comprising at least 100 kb of xenogeneic DNA (YACS), classified in Class 800, subclass 2, for example.

IX. Claims 60-66, drawn to a method for modifying a genome of a recipient murine embryonic stem cell by homologous recombination with a large xenogeneic DNA genomic fragment previously manipulated in a yeast artificial chromosome (YAC), classified in Class 435, subclass 172.3, for example.

X. Claims 70 and 71, drawn to a human antibody molecule, classified in Class 530, subclass 388.15, for example.

XI. Claims 72-74, drawn to a method for producing a genetically modified non-human animal, comprising interbreeding a first parent and a second parent, classified in Class 435, subclass 172.3, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I and II) and Invention III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed (the xenogeneic immunoglobulin) can be made by a materially different process such as either of those of Inventions I or II or by chemical synthesis, for example.

Invention IV (a genetically modified non-human animal) and Inventions I (method for producing a xenogeneic immunoglobulin) and X (interbreeding animals to obtain progeny) are related as product and process of use. The inventions can be shown to be distinct if either or both of the

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following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in either of the materially different processes such as animal husbandry (Invention X) or to produce xenogenic immunoglobulins (Invention IV), for example.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case Invention VI (transgenic non-human animal) can be made by another and materially different process such as by interbreeding two mice already having genomes containing at least 100 kb of DNA stably integrated in their genome, for example.

Inventions VIII and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case Invention VIII (embryonic stem cells comprising at least 100 kb of DNA) can be used in a materially different process such as further genetic studies on the carried xenogeneic DNA, for example.

Inventions VII (embryonic stem cells) and IX (method of modifying the genome of a recipient murine embryonic stem cell) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product (stem cell) could be used in a materially different process such as genetic studies of stem cells per se, for example .

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)308-4227.

An inquiry concerning this communication should be directed to Examiner Suzanne Ziska, Ph.D., at telephone number 703-308-1217.

Suzanne Ziska

SUZANNE E. ZISKA
PRIMARY EXAMINER
GROUP 1800
4/5/94

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